

510(K) SUMMARY

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR §807.92.

The assigned 510(k) number is: K062867

1. Submitter's Identification:

Microlife Intellectual Property GmbH, Switzerland
Max Schmidheiny-Strasse 201
9435 Heerbrugg / Switzerland

Date Summary Prepared: Aug 15, 2006

2. Name of the Device:

Microlife Instant Digital Electronic Thermometer, Model QT1JC1

3. Predicate Device Information:

Microlife Instant Digital Electronic Thermometer, Model QT1JA1, K#031958,

4. Device Description:

This Instant thermometer enables very fast and reliable measurements and with its predicative technology the thermometer offers a very high clinical accuracy and has been designed to provide a maximum of user- friendliness

The basic principle of this thermometer is that change of thermistor resistance, caused by changes of temperature, are converted to changes of frequency of R-C oscillator circuit. Therefore, temperature can be given by measuring the frequency of oscillator.

For a give time period (to), by applying to R-C oscillator circuit, changes of temperature will correspond to changes of pulse number

5. Intended Use:

Microlife QT1JC1 Instant Thermometer is used for the intermittent measurement and monitoring of human body temperature, orally, rectally and under the arm.

The Microlife QT1JC1 Instant Thermometer is a hand- held, non-sterile, reusable clinical thermometer intended for the determination of human temperature in either predictive (Instant) mode (5-seconds in oral and rectal mode, 8-seconds

in under the arm mode—predicative temperature) , or standard mode (actual determination of temperature).

The device is for the adult and pediatric population.

6. Comparison to Predicate Devices:

The Microlife Instant Thermometer, Model QT1JC1 is substantially equivalent to Microlife instant Thermometer, Model QT1JA1, K#031958 which have the same intended use and are similar in design to the predicate device.

The Microlife Instant Thermometer QT1JC1 and the predicate device are identical in functionality and performance with the difference being the external shape of the devices, and PCB layout of the devices, include performance specifications, ergonomics of the user interface, dimensional specifications. The temperature measurements algorithm and its fundamental scientific technology are identical to the predicate device.

7. Discussion of Non-Clinical Tests Performed for Determination of Substantial Equivalence are as follows:

Compliance to applicable voluntary standards includes ASTM E1112, as well as IEC60601-1 and IEC60601-1-2 requirements.

Guidance documents included the "FDA Guidance on the Content of Premarket Notification 510(K) Submissions for Clinical Electronic Thermometers.

8. Discussion of Clinical Tests Performed:

Controlled human clinical studies were conducted using the Microlife Instant Digital Electronic Thermometer, Model QT1JC1. Clinical data was presented which evaluated clinical bias, clinical uncertainty and clinical repeatability per the Microlife Clinical Test Protocol outline.

9. Conclusions:

The Microlife Instant Digital Electronic Thermometer, Model QT1JC1 has the same intended use and similar technological characteristics as the Microlife Instant Thermometer, Model QT1JA1. Moreover, bench testing contained in this submission supplied demonstrates that any differences in their characteristics do not raise any new questions of safety or effectiveness. Thus, the Microlife Instant Digital Electronic Thermometer, Model QT1JC1 is substantially equivalent to the predicate device.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Microlife Intellectual Property, GmbH
C/O Ms. Susan D. Goldstein-Falk
Official Correspondent
MDI Consultants, Incorporated
55 Northern Boulevard, Suite 200
Great Neck, New York 11021

DEC - 6 2006

Re: K062867

Trade/Device Name: Microlife Instant Digital Electronic Thermometer,
Model QT1JC1

Regulation Number: 880.2910

Regulation Name: Clinical Electronic Thermometer

Regulatory Class: II

Product Code: FLL

Dated: November 16, 2006

Received: November 17, 2006

Dear Ms. Goldstein-Falk:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

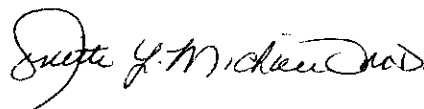
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address <http://www.fda.gov/cdrh/industry/support/index.html>.

Sincerely yours,

A handwritten signature in black ink, appearing to read "Chiu Lin, Ph.D.", written in a cursive style.

Chiu Lin, Ph.D.

Director

Division of Anesthesiology, General Hospital,

Infection Control and Dental Devices

Office of Device Evaluation

Center for Devices and

Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K062867

Device Name: Microlife Instant Digital Thermometer, Model QT1JC1

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The device is for the adult and pediatric population.

Prescription Use _____
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use X _____
(21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE
OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)



(Signature-Off)
Dr. H. L. Brown
Dept of Anesthesiology, General Hospital,
Drug Control, Dental Devices

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